RESPONSE UNDER 37 C.F.R. § 1.111 Attorney Docket No.: Q92427

Application No.: 10/563,560

REMARKS

Review and reconsideration on the merits are requested.

The only rejection posed was an art rejection.

Claims 1-4 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S.

6,201,072 Rathi et al (Rathi).

This rejection is respectfully traversed.

The Examiner's position is set forth in the Action and will not be repeated here in detail

except as necessary to an understanding of Applicants' traversal which is now presented.

Traversal

Applicant agrees with the Examiner that Rathi discloses a water soluble, biodegradable

ABA triblock polymer, but does not agree that Rathi teaches an A polymer block having a

depsipeptide unit, which is the essential feature of the present invention.

Rathi teaches that the ABA triblock polymer of Rathi consists of a hydrophobic A

polymer block comprising a biodegradable polyester and a hydrophilic B polymer block

consisting of polyethylene glycol (PEG). The hydrophobic A polymer is a polyester, and does

not have amide bonds, which are contained in a depsipeptide, a copolymer of an alpha-amino

acid and an alpha-hydroxycarboxylic acid.

As described at page 2, lines 10-22 of the present specification as well as in the prior art,

it is known that in conventional block copolymers of a polylactide (polyester) and PEG,

mechanical strength and flexibility and water absorbability are conflicting properties. To

achieve sufficient flexibility and water absorbability, the polymerization degree of the

polylactide must be reduced, which, of course, lowers mechanical strength. On the other hand, if

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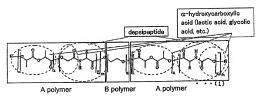
the polymerization degree of the polylactide is increased, flexibility and water absorbability are deteriorated.

In view of such disadvantages of the conventional block copolymers of a polylactide (polyester) and PEG, the present invention provides a biocompatible material having excellent flexibility and water absorbability which is suitable for clinical use, which could not be obtained with aliphatic polyesters, such as a polylactide.

With a depsipeptide unit contained therein, the triblock copolymer of the present invention has excellent flexibility and tissue anti-adhesion property, as well as bioabsorbability, and is excellently suitable for use in the medical field.

In order to explain in detail the difference between the present invention and Rathi, a specific example of the triblock copolymer of the present invention as defined in claim 4 and the compound disclosed in Rathi are compared below.

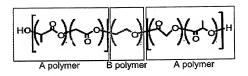
An example of the present triblock copolymer is represented by the formula (1) given in claim 4:



The triblock copolymer, PLGA-PEG-PLGA, disclosed in Example 1 of Rathi is represented by the following formula:

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As can be seen from the above, the compounds of the present invention and Rathi are both ABA triblock copolymers, but have A polymer blocks of different structures. More specifically, both copolymers have an alpha-hydroxycarboxylic acid monomer in the A polymer block, but only the copolymer of the present invention has the depsipeptide unit of a copolymer of an alpha-amino acid and an alpha-hydroxycarboxylic acid in the A polymer block. This depsipeptide unit is not present in the A polymer block of Rathi.

The Examiner further urges that Rathi discloses an A polymer block having an Mw of about 600 to 3000 and a B polymer block having the Mw of about 500 to 2200. Taking into consideration that the triblock copolymer requires two A components and one B component and that the Mw/Mn ratio is 1.4, the Mn of the triblock copolymer of Rathi would be overlap with those in claim 1.

However, conversion of Mw to Mn is not as simple as the Examiner urges, and it is not appropriate to compare the Mw disclosed in Rathi with the Mn defined in the present claims in the manner as the Examiner has done.

It is known that, for the same substance, the value of Mn is always smaller than the value of Mw. Considering the disclosure in Rathi that the overall Mw of the tri-block polymer is between about 2000 and 4990 (see Abstract, claim 1, etc.), it is evident, even without conversion,

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that the molecular weight of the tri-block polymer of Rathi is much lower than the claimed range

of 8,000 to 500,000 of the present invention.

As described at page 11, lines 17-18 of the present specification, at an Mn less than

8,000, the properties expected and desired in medical use may not be shown.

In sum, Applicants respectfully submit that in the absence of disclosure in Rathi of the

depsipeptide unit and the number average molecular weight of the triblock copolymer defined in

the present claims, the present invention is not obvious over Rathi.

Withdrawal is requested.

In view of the above, reconsideration and allowance of this application are now believed

to be in order, and such actions are hereby solicited. If any points remain in issue which the

Examiner feels may be best resolved through a personal or telephone interview, the Examiner is

kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue

Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any

overpayments to said Deposit Account.

Respectfully submitted,

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